

**510(k) Summary for  
Dimension Vista™ MALB Flex® reagent cartridge  
Dimension Vista™ Protein 3 Calibrator  
Dimension Vista™ Protein 3 Control**

SEP 19 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K061990

**1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Marburg GmbH  
Emil-von-Behring Str. 76  
D-35001  
Marburg, Germany

Contact Information: Dade Behring Inc.  
P.O. Box 6101  
Newark, Delaware 19714-6101  
Attn: Kathleen Dray-Lyons  
Tel: 781-826-4551  
Fax: 781-826-2497

Preparation date: July 11, 2006

**2. Device Name:** Dimension Vista™ Microalbumin Flex® reagent cartridge (MALB)  
Dimension Vista™ Protein 3 Calibrator  
Dimension Vista™ Protein 3 Control

**Classification:** Class II; Class II; Class I

**Product Code:** DCF; JIX; JJY

**Panel:** Immunology (82) and Clinical Chemistry (75)

**3. Identification of the Legally Marketed Device:**

Dade Behring N Antiserum to Human Albumin – K860894

Dade Behring N Protein Standard SL – K012470

Dade Behring N/T Protein Control LC – K991704

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**4. Device Description:**

**Dimension Vista™ MALB Flex® reagent cartridge**

Proteins contained in human urine form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of albumin in the sample. The result is evaluated by comparison with a standard of known concentration.

**Dimension Vista™ Protein 3 Calibrator**

PROT3 CAL is a lyophilized, polygeline based (with urinary proteins of human origin) product containing Albumin.

**Dimension Vista™ Protein 3 Control**

PROT3 CON is a lyophilized, polygeline and albumin based product containing albumin of human origin.

**5. Device Intended Use:**

**Dimension Vista™ MALB Flex® reagent cartridge:**

The MALB method is an *in vitro* diagnostic reagent for the quantitative determination of albumin in human urine on the Dimension Vista™ System. Measurement of Albumin aids in the diagnosis of kidney and intestinal disease.

**Dimension Vista™ Protein 3 Calibrator:**

Protein 3 Calibrator is an *in vitro* diagnostic product for the calibration of the Microalbumin (MALB) method on the Dimension Vista™ System.

**Dimension Vista™ Protein 3 Control:**

Protein 3 Control is an assayed intralaboratory quality control for the assessment of precision and analytical bias in determination of Microalbumin (MALB) on the Dimension Vista™ System.

**6. Medical device to which equivalence is claimed and comparison information:**

The Dimension Vista™ MALB Flex reagent cartridge, Dimension Vista™ Protein 3 Calibrator and Dimension Vista™ Protein 3 Control are substantially equivalent to the Dade Behring N Antiserum to Human Albumin assay (K860894) assay, N Protein Standard SL (K012470) and N/T Protein Control LC (K991704), respectively. The Dimension Vista™ MALB assay, like the Dade Behring N Antiserum to Human Albumin assay is an *in vitro* diagnostic reagent for the quantitative measurement of Microalbumin (MALB) in human urine by means of particle enhanced immunonephelometry.

**7. Device Performance Characteristics:**

The Dimension Vista™ MALB assay was compared to the Dade Behring N Antiserum to Human Albumin assay on the BN ProSpec® System by evaluating urine samples with concentrations ranging from 5.87 to 332.74 mg/L. Regression analysis of these results yielded the following equation:

**Method Comparison Study**

	<b>n</b>	<b>Slope</b>	<b>Intercept</b>	<b>Correlation Coefficient</b>
Dimension Vista™ MALB	74	0.988	-0.936	0.996



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP 19 2006

Ms. Kathleen Dray-Lyons  
Dade Behring, Inc.  
P.O. Box 6101  
Newark, DE 19714-6101

Re: k061990  
Trade/Device Name: Dimension Vista™ MALB Flex® reagent cartridge  
Dimension Vista™ Protein 3 Calibrator  
Dimension Vista™ Protein 3 Control  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: DCF, JIT, JJY  
Dated: July 11, 2006  
Received: July 13, 2006

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

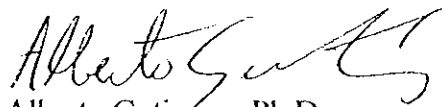
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", is positioned above the printed name.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications Statement

**Device Name:**      **Dimension Vista™ MALB Flex® reagent cartridge**  
                         **Dimension Vista™ Protein 3 Calibrator**  
                         **Dimension Vista™ Protein 3 Control**

### Indications for Use:

#### **Dimension Vista™ MALB Flex® reagent cartridge:**

The MALB method is an *in vitro* diagnostic reagent for the quantitative determination of albumin in human urine on the Dimension Vista™ System. Measurement of albumin aids in the diagnosis of kidney and intestinal disease.

#### **Dimension Vista™ Protein 3 Calibrator:**

Protein 3 Calibrator is an *in vitro* diagnostic product for the calibration of the Microalbumin (MALB) method on the Dimension Vista™ System.

#### **Dimension Vista™ Protein 3 Control:**

Protein 3 Control is an assayed intralaboratory quality control for the assessment of precision and analytical bias in determination of Microalbumin (MALB) on the Dimension Vista™ System.

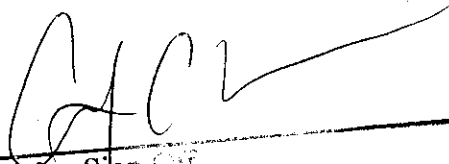
Prescription Use   X    
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
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Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
510(k) K061990

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